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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,221	08/10/2001	Joel R. Haynes	DE-3-C2-PUS	3163

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EXAMINER	
FOLEY, SHANON A	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 09/24/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/830,221	HAYNES ET AL.	
	Examiner	Art Unit	
	Shanon Foley	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 April 2003 and 14 July 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18 and 20-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18 and 20-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

In paper no. 18, applicant amended claims 1-5, 16 and 21-25. Claims 1-18 and 20-27 are under consideration.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-18 and 20-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCluskie et al. (Antisense and Nucleic Acid Drug Development. 1998; 8: 401-414), Ray et al. (Vaccine. 1997; 15 (8): 892-895) and Paoletti (US 5,505,941).

Claims 1-2 are drawn to delivering a purified nucleic acid and a method of eliciting an immune response (claim 5) to an antigen in a felid (claims 15-17) by administering (claim 20) the nucleic acid encoding an antigen (claims 4 and 6) complexed with a cationic lipid. The specific cationic lipid is tetramethyltetraalkyl spermine analog lipid (claim 13). The composition elicits an antibody (claim 7) and a cell-mediated response (claim 8) and protects the felid against disease (claim 9) and results in 75-100% seroconversion rate (claims 21 and 22). The composition is administered in a single administration (claim 18) and also comprises an immunomodulator (claim 14) or an excipient (claim 27). The antigen is any feline disease antigen, but is more specifically a rabies glycoprotein G (claims 10-12). The nucleic acid : lipid concentration ranges between 1:10 and 10:1 (claim 23) with the nucleic acid present in a dose of not more than 75 micrograms (claim 25) or ranges from 75-1000 micrograms (claim 24) and is

dehydrated and rehydrated prior to administration (claim 26). Claim 3 is drawn to a method of protecting a felid from rabies infection by administering a nucleic acid encoding rabies glycoprotein G complexed to a cationic lipid.

Ray et al. teach a method of inducing a protective serum neutralizing antibody response against rabies by intramuscularly or intradermally administering a plasmid encoding rabies glycoprotein G in a suitable carrier. The plasmids are delivered alone or in combination with and without cardiotoxin or MPL. See "Plasmid constructions", "Enhancement of the immune response", the "Results" section and Figure 1.

Ray et al. do not teach complexing the nucleic acid with cationic lipid tetramethyltetraalkyl spermine analog, inducing a cell-mediated response, the instant dose ranges of the DNA, or the nucleic acid to lipid ratio.

However, McCluskie et al. teach conventional therapeutic immunomodulators that induce specific cell-mediated responses, see the introduction section on pages 401-402. McCluskie et al. also teach complexing plasmid DNA with tetramethyltetraalkyl spermine analog lipid within the range of the instant DNA:lipid ratio claimed and administering up to 100 micrograms of plasmid DNA, see "Cationic and neutral lipids" , "Preparation of liposomes" and "Preparation of plasmid-liposome DNA complexes" on pages 402-403.

One of ordinary skill in the art at the time the invention was made would have been motivated to incorporate the DNA vaccine of Ray et al. et al. with the cationic lipid of McCluskie et al. to obtain better transfection efficiencies, increase retention times and reduce the rate of degradation, see the first full paragraph of page 409 and the paragraph bridging pages 409-410 of McCluskie et al. One of ordinary skill in the art at the time the invention was made

would have had a reasonable expectation for combining the plasmid vaccine of Ray et al. with the cationic lipid formulation of McCluskie et al. because McCluskie et al. teach using plasmid DNA because it is easy to produce, nonimmunoenic and does not result in inadvertent infection, see the introduction section, and Ray et al. vaccinate using a plasmid.

Although neither reference teaches dehydrating and rehydrating the formulation, lyophilized vaccine formulations are conventionally used in the vaccine art. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art, absent unexpected results to the contrary.

Neither Ray et al. nor McCluskie et al. teach immunizing cats. However, Paoletti teach vaccinating cats against rabies with a recombinant avipox encoding rabies glycoprotein G, see claims column 15, lines 26-44 and Table VI, and column 35, lines 30-50 and Table XIV.

One of ordinary skill in the art at the time the invention was made would have been motivated to vaccinate cats against rabies with the plasmid-cation lipid construct of Ray et al. and McCluskie et al. to protect cats against rabies virus infection, see the previous citations of Paoletti. One of ordinary skill in the art at the time the invention was made would have been motivated to vaccinate cats against rabies with the plasmid-cation lipid construct of Ray et al. and McCluskie et al. because plasmid vaccines are easy to produce, nonimmunoenic and do not result in inadvertent infection as with a viral vaccine, see the introduction section of McCluskie et al. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of immunizing cats taught by Paoletti with the plasmid-cation lipid construct of Ray et al. and McCluskie et al. because both Paoletti and Ray et al. observe protective neutralizing antibody responses with the same rabies glycoprotein G antigen.

Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results to the contrary.

Applicant argues Paoletti does not teach or suggest administering purified DNA.

In response, the deficiency in Paoletti is remedied by the teachings of Ray et al.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Shanon Foley

JAMES HOUSEL 9/22/03
SUPERVISORY PATENT EXAMINER